Complete Summary

GUIDELINE TITLE

Antenatal corticosteroids to prevent respiratory distress syndrome.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Antenatal corticosteroids to prevent respiratory distress syndrome. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Feb. 9 p. (Guideline; no. 7). [53 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Respiratory distress syndrome, neonatal death, and intraventricular haemorrhage associated with preterm delivery

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology
Pediatrics
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Hospitals
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide up to date information on the appropriate use of antenatal corticosteroid therapy prior to preterm delivery for the reduction of neonatal mortality and morbidity
- To discuss other therapeutic interventions that may increase or decrease the effects of corticosteroids (i.e., tocolytics and thyrotrophin-releasing hormone)

Note: This guideline does not address measures designed to predict preterm delivery (i.e., ultrasound scanning for cervical length, cervical fibronectin measurement, or bacterial screening of mothers), nor does it address other interventions that may reduce the mortality and morbidity from preterm labour (i.e., antibiotics for preterm prelabour rupture of membranes [PPROM]).

TARGET POPULATION

Pregnant women at risk of preterm delivery

INTERVENTIONS AND PRACTICES CONSIDERED

1. Antenatal corticosteroid therapy (betamethasone)
2. Tocolytics (atosiban, nifedipine)
3. Patient education programs

Thyrotrophin-releasing hormone was considered but not recommended.

MAJOR OUTCOMES CONSIDERED

- Neonatal mortality and morbidity, including incidence of respiratory distress syndrome (RDS), neonatal death, and intraventricular haemorrhage
- Side effects of pharmacological therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Cochrane Database of Systematic Reviews and the Cochrane Controlled Trials Register Issue 4, 2002, were searched for relevant randomized controlled trials (RCTs), systematic reviews, and meta-analyses. The electronic databases Medline (1996-2002) and Embase (1996-2002) were searched for further studies published since the last revision of the guideline in December 1999. The principle Medical Subject Heading (MeSH) terms used were "steroids," "premature labour," "premature fetus," and "membrane rupture."

The Internet databases, National Guidelines Clearing House, National Electronic Library for Health, OMNI, e-guidelines, TRIP database, and Health Evidence Bulletins Wales, were searched for national and international guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based. The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group of the National Health Service (NHS) Executive.

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

COST ANALYSIS

The cost and duration of neonatal intensive care is reduced following corticosteroid therapy. However, the overall economic effect of antenatal corticosteroids will be influenced by the potential increase in survival of very-low-birth weight babies and by the use of surfactant. An increase in use from 15% to 60% in babies of less than 2,000 grams born in the USA would result in an annual saving of US$157 million (equivalent to 94.2 million pounds sterling at October 2003 currency exchange rates). A more modest saving to the National Health Service (NHS) has been predicted, although the costs of treating low-birthweight infants remain considerable.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following discussion in the Guidelines and Audit Committee, each green-top guideline is formally peer reviewed. At the same time the draft guideline is

published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

The names of author(s) and nominated peer reviewers are included in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Levels of evidence (Ia-IV) and grading of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

Effectiveness of Antenatal Corticosteroid Therapy

A - Clinicians should offer antenatal corticosteroid treatment to women at risk of preterm delivery because antenatal corticosteroids are associated with a significant reduction in rates of respiratory distress syndrome (RDS), neonatal death, and intraventricular haemorrhage.

B - Healthcare organisations and services should have policies and protocols in place for antenatal steroid treatment because the cost and duration of neonatal intensive care is reduced following corticosteroid therapy.

A - The optimal treatment-delivery interval for administration of antenatal corticosteroids is more than 24 hours but fewer than seven days after the start of treatment.

A - In preterm labour it is reasonable not to use tocolytic drugs, as there is no clear evidence that they improve outcome. However, clinicians should consider the use of short-term tocolysis if the few days gained can be put to good use, such as completing a course of corticosteroids, or in utero transfer.

A - If a tocolytic drug is used, ritodrine no longer seems to be the best choice. Atosiban or nifedipine appear to be preferable, as they have fewer adverse effects and seem to have comparable effectiveness. Atosiban is licensed for this usage in the United Kingdom (UK) but nifedipine is not.

Safety

A - Women may be advised that the use of a single course of antenatal corticosteroids does not appear to be associated with any significant maternal or fetal adverse effects.

Indications for Antenatal Corticosteroid Therapy

A - Every effort should be made to initiate antenatal corticosteroid therapy in women between 24 and 34 weeks of gestation with any of the following:

- Threatened preterm labour
- Antepartum haemorrhage
- Preterm rupture of membranes
- Any condition requiring elective preterm delivery

Between 35 to 36 weeks obstetricians might want to consider antenatal steroid use in any of the above conditions although the numbers needed to treat will increase significantly. [Evidence level Ia]

Antenatal education programmes or patient information leaflets should be considered to encourage early recognition of these conditions, in an effort to ensure early presentation and commencement of treatment. Maternity services should consider multidisciplinary staff training in providing information, including risk ratios, to women.

Dose and Route of Administration

B - Betamethasone is the steroid of choice to enhance lung maturation. Recommended therapy involves two doses of betamethasone 12 mg, given intramuscularly 24 hours apart.

Repeated Doses

A - If repeat courses of antenatal corticosteroids are contemplated then senior opinion should be sought as, at present, there is a lack of evidence to show significant benefit.

A - Obstetricians should consider enrolling their patients in randomised controlled trials if repeat corticosteroid therapy is contemplated.

Effectiveness of Thyrotrophin-Releasing Hormone

A - The use of thyrotrophin-releasing hormone is not recommended in combination with antenatal corticosteroids.

Definitions:

Grading of Recommendations:

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

Levels of Evidence:

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate antenatal treatment with corticosteroids, which may reduce the incidence of respiratory distress syndrome (RDS), neonatal death, and intraventricular haemorrhage

POTENTIAL HARMS

None stated

CONTRAINDICATIONS

CONTRAINDICATIONS

Corticosteroid therapy is contraindicated if a woman suffers from systemic infection including tuberculosis. Caution is advised if suspected chorioamnionitis is diagnosed.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Clinical guidelines are "systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions." Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: Guidance for the Development of Royal College of Obstetricians & Gynaecologists (RCOG) Green-top Guidelines.
- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution, and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Antenatal corticosteroids to prevent respiratory distress syndrome. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Feb. 9 p. (Guideline; no. 7). [53 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Apr (revised 2004 Feb)

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

Royal College of Obstetricians and Gynaecologists

GUIDELINE COMMITTEE

Guidelines and Audit Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor Deirdre J Murphy, MRCOG (Chair); Lizzy Dijeh (Secretary); Ms Toni Belfield, Consumers' Representative; Professor P R Braude, FRCOG, Chairman, Scientific Advisory Committee; Mrs C Dhillon, Head of Clinical Governance and Standards Dept.; Dr Martin Dougherty, A. Director NCC-WCH; Miss L M M Duley, FRCOG, Chairman, Patient Information Subgroup; Mr Alan S Evans, FRCOG; Dr Mehmet R Gazvani, MRCOG; Dr Rhona G Hughes, FRCOG; Mr Anthony J Kelly MRCOG; Dr Gwyneth Lewis, FRCOG, Department of Health; Dr Mary A C Macintosh, MRCOG, CEMACH; Dr Tahir A Mahmood, FRCOG; Mrs Caroline E Overton, MRCOG, Reproductive medicine; Dr David Parkin, FRCOG; Oncology; Ms Wendy Riches, NICE; Mr Mark C Slack, MRCOG, Urogynaecology; Mr Stephen A Walkinshaw, FRCOG, Maternal and Fetal Medicine; Dr Eleni Mavrides, Trainees Representative

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Guideline authors are required to complete a "declaration of interests" form.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the RCOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Guidance for the development of RCOG green-top guidelines. Clinical Governance Advice No 1. 2000 Jan. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Searching for evidence. Clinical Governance Advice No 3. 2001 Oct. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Additionally, Audit Standards can be found in section 10 of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

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